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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,981	07/28/2003	Saul Yedgar	P-2507-US1	4110
27130	7590	05/04/2005	EXAMINER	
EITAN, PEARL, LATZER & COHEN ZEDEK LLP 10 ROCKEFELLER PLAZA, SUITE 1001 NEW YORK, NY 10020			O SULLIVAN, PETER G	
			ART UNIT	PAPER NUMBER
			1621	

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/627,981	Applicant(s) YEDGAR ET AL.	
	Examiner Peter G. O'Sullivan	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Claims 1-18 are pending in this application which should be reviewed for errors. In response to the requirement for the election of a single disclosed species, applicants' elected phosphatidylethanolamines bound to hyaluronic acid of the formula given on page 2 of their response. Applicants' phosphatidylethanolaminoglycosaminoglycans are examined therewith with all other compounds held withdrawn.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-12 provides for the use of applicants' compounds, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 7-12 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 13-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Aoki et al., US 5,470,578, who disclose anticipating chondroitin and hyaluronic acid derivatives in the examples.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teaching of Yedgar et al., US 5,064,817, Chaikof et al., US 6,171,614, and Aoki et al., US 5,470,578, in view of Pruzanski et al., US 6,043,231, Sorgente et al., US 6,162,787, and Falk et al. US 6,022,866. Yedgar et al. disclose anti-inflammatory derivatives including distearoyl phosphatidylethanolamines covalently bonded through the amine group to carrier moieties which may include polysaccharides (s. Col. 2, ll. 50-58 and Col. 4, ll. 43-59). Yedgar et al. disclose their compounds to be PLA2 inhibitors

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thus having utility in a wide variety of oversecretory disease states such as allergic response, inflammation, atherosclerosis, thrombosis, etc. (Col. 13, top and middle). Although chondroitin and hyaluronic acid are not specifically mentioned by Yedgar et al. as carrier moieties, their listing is clearly not meant to be exhaustive. Chondroitin sulfate and hyaluronic acid are polysaccharides. Chaikof et al. disclose targeting of therapeutic agents using glycopospholipids generically overlapping applicants (s. Col. 3, bottom). Chaikof et al. disclose the saccharide derivative used in the glycopospholipid may itself be therapeutic and specifically mentions chondroitin sulfate (s. Col. 5, second and third paragraphs). Aoiki et al. disclose antirheumatic compositions generically overlapping applicants' with anticipating examples (s. examples).

The instant invention differs from the teaching of the cited references in that applicants' sepsis utility is not disclosed and in that other compounds are claimed which are not specifically exemplified. Pruzanski et al. is relied on to teach PLA2 inhibiting compounds to be useful in treating sepsis and various inflammatory disorders. Sorgente et al. disclose chondroitin sulfate to be useful as an anti-inflammatory. Falk et al. is relied on to teach hyaluronic acid itself to be useful in the atherosclerotic process of restinosis. Especially in view of the teaching of Chaikof et al. that the saccharide derivative itself may be therapeutic, it would have been prima facie obvious at the time the invention was made to start with the teaching of the cited references, to make applicants compounds and to expect to produce compounds and compositions useful as anti-inflammatory agents or agents in the treatment of disease states such as

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atherosclerosis, sepsis, etc. To make further compounds generically disclosed, but not specifically exemplified would be further prima facie obvious in view of close or anticipating compounds already made.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).


Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 09/756,765. Although the conflicting claims are not identical, they are not patentably distinct from each other because applicants' compositions would be obvious over their compounds.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Any inquiry concerning this communication should be directed to Peter G. O'Sullivan at telephone number (571)272-0642.


PETER O'SULLIVAN
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